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08/469,637 06/06/95 GREENE

J	EXAMINER 0-381
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18N2/0930

ART UNIT	PAPER NUMBER
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DATE MAILED:

09/30/96

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

- ☒ *FOR RESTRICTION PURPOSE ONLY* This application has been examined, ☐ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 0 month(s), 30 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.             | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152.       |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____   |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-20 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☐ Claims \_\_\_\_\_ are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☒ Claims 1-20 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

1. The preliminary amendment has been entered.

*Election/Restriction*

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, drawn to an isolated polynucleotide, a vector, a host cell, a process of producing polypeptide, and a process for producing cells, classified in Class 435, subclass 69.1.

II. Claims 8 and 19, drawn to a polypeptide, classified in Class 530, subclass 300+.

III. Claim 9, drawn to an antibody, classified in Class 530, subclass 387.1.

IV. Claim 10 and 12, drawn to a compound which activates, and a method for the treatment having the need of activation of a TNF receptor, classification unknown because no structural information is provided.

V. Claim 11 and 13, drawn to a compound which inhibits activation and drawn to a method for the treatment of a patient having a need to inhibit activation of a polypeptide, classification unknown because no structural information is provided.

VI. Claim 14, drawn to a method for the treatment using DNA encoding agonist, classified in Class 514, subclass 44.

VII. Claim 15, drawn to a method for the treatment using DNA encoding antagonist, classified in Class 514, subclass 44.

VIII. Claim 16 and 17, drawn to a method for identifying compounds, Class 435, subclass 7.2.

IX. Claim 18, drawn to a process for diagnosing a disease, classified in Class 435, subclass 6.

X. Claim 20, drawn to a diagnostic process, classified in Class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-V are distinct each from the other, because they are drawn to compositions having materially different structures and functions. The polynucleotide, vector, and cell of I are different from the polypeptide of II and the antibodies of group III, the activating compound of IV, and the inhibiting compound of V.

Inventions I and IV-X are distinct, each from the other, because they are drawn to processes having materially different process steps, which are practiced for materially different purposes. The polynucleotide, vector, or cell of I is not used in or produced by the methods of IV, V, VIII, or IX.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can

be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the protein of II can be made by protein purification from cells endogenously expressing the protein.

Inventions I and VI, VII, and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a any of the materially different processes of using that product such as any of I, VI, VII, or IX.

The polypeptide of II is not used in or produced by the processes of IV-IX.

Inventions II and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in materially different process such as producing

antibodies.

The antibody of III is not used in or produced by the processes of I, or IV-IX.

Inventions III and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of III can be used to treat a TNF receptor mediated disease.

The activating compound of IV is not used in or produced by the processes of I, or V-X.

The inhibiting compound of V is not used in or produced by the processes of I, IV or VI-X.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications and because of their recognized divergent subject matter, and because the search required for each group is not required for any of the others, restriction for examination purposes as indicated is proper.

A telephone call was made to J. Mullins on 27 August 1996 to request an oral election to the above restriction requirement, but did not result in an election being made.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Pak whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Walsh, can be reached on (703) 308-2957. The fax phone number for this Group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*MDP*

Michael D. Pak  
1812  
23 September 1996

*Stephen Walsh*  
**STEPHEN G. WALSH**  
**PRIMARY EXAMINER**  
**GROUP 1800**